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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,431	03/28/2002	Kakuji Tojo	13357.4USWO	6928
23552	7590	02/23/2005	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,431

Applicant(s)

TOJO ET AL.

Examiner

Micah-Paul Young

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,8-12,16,18-21,25,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,8-12,16,18-21,25,27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Request for Continued Examination dated 11/01/04.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,6,8-12,16,18-21,25,27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Deurer et al (USPN 5,869,086 hereafter '086), Godbey (USPN 6,086,911 hereafter '911) and Fukiage et al (EP 0 771 565 hereafter '565).

Claims 1-2, and 6 are drawn to an ophthalmic transdermal patch comprising a drug and penetration enhancers. Claims 11-12, and 16 are drawn to a method of treating a disease of the eye using the patch of the invention. Claims 12, 16 and 18 – 20 recite a method for the treatment of a disease of the eye. The treatment comprises applying the transdermal patch of claims 1,2,6,8 – 10.

'086 et al discloses a transdermal patch for the treatment of glaucoma. The patch comprises an active agent that can treat the disease of the eye. The patch comprises an acrylic polymer based matrix, which further comprises penetration enhancers such as isopropyl myristate and oleyl alcohol. The patch was administered to patients for the treatment of the disease

Art Unit: 1615

(col. 3, lin. 38 – 60; col. 4, lin. 22 – 25; examples). What is lacking in this reference is a disclosure of polyoxyethylene oleyl ethers as possible penetration enhancers.

The '911 patent discloses a transdermal matrix formulation comprising a matrix, backing sheet and various penetration enhancers (col. 4, lin. 38 – 58). The penetration enhancers include fatty acid esters such as isopropyl myristate and polyoxyethylene oleyl ethers 2 and 10 (col. 6, lin. 28 – 53). It would have been obvious to a skilled artisan to combine the enhancers of '911 with the formulation of '086 in order to improve the transmission of active agents across the mucosa.

What is lacking in the references is a teaching of the N-(4-fluorophenylsulfonyl)-L-valyl-L-leucinal drug recited in claims 9, 10, 19 and 20. This ophthalmic drug and its salts are well known in the art and have been disclosed by '565. The '565 patent discloses that the drug can be useful in treating disorders eye, specifically the retina, and also discloses that transdermal delivery is possible (Abstract; pg. 2, lin. 49 – 52; formula (VI), pg. 4; pg. 13, lin. 45 – 50; pg. 38, lin. 2 – 11).

With regard to the claims, which recite specific ranges and concentrations of the penetration enhancers and polymer ratios, it is the position of the examiner that such recitations are non-critical to the patentability of the invention. Applicant is reminded that it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various transdermal compositions having

Art Unit: 1615

various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to a skilled artisan to combine the penetration enhancers of '911 with the formulation of '086 in order to improve the transmission of active agents across the mucosa membrane. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). A skilled artisan would have been further motivated to substitute the active agent of '565 into the transdermal patch combination of '086 and '911 in order to treat disorders of the eye, along with possibly Alzheimer's symptoms. It would have been obvious to combine these teachings and optimize their concentrations with an expected result of an ophthalmic transdermal patch that was useful in treating diseases of the eye.

Response to Arguments

3. Applicant's arguments filed 09/03/04 have been fully considered but they are not persuasive. Applicant argues that:

a. Godbey does not provide motivation to combine isopropyl myristate and polyoxyethylene oleyl ether at the concentrations of the instant claims.

4. Regarding applicant's argument it is the position of the Examiner that there exists sufficient motivation to combine these components. The compounds are well known penetration

Art Unit: 1615

enhancers, as shown in Deurer and Godbey. Their functions are well known to artisans of ordinary skill and it is obvious to combine like components in order to increase their effects. As discussed above it would have been obvious to combine the two penetration enhancers in order to increase the penetration of the active agents, especially where the result is additive, as shown in applicant's specification. Burden was shifted to applicant to provide unexpected results from the combination that would lend patentable weight to the limitations. However, after careful review of applicant's data, it can be seen that the results from the combination of isopropyl myristate and polyoxyethylene oleyl are additive. An additive effect, as discussed above, is in fact an expected result from one of ordinary skill in the art, from the combination of two well-known constituents within the same field of endeavor. Applicant has not provided any unexpected results from the combination of the two penetration enhancers, and without such results the claims will remain obviated by the combination of Deurer, Godbey and Fukiage.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

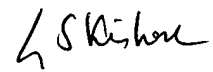
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MP Young

Micah-Paul Young
Examiner
Art Unit 1615


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For TK Page